DRAFT MINUTES OF THE MEETING OF THE SECRETARY OF STATE FOR TRANSPORT'S HONORARY MEDICAL ADVISORY PANEL ON DRIVING AND DISORDERS OF THE CARDIOVASCULAR SYSTEM

THURSDAY, 19 SEPTEMBER 2013

Present:	Dr M J Griffith	Chairman
	Dr L Freeman	
	Professor C Garratt	
	Mr A Goodwin	
	Dr R Henderson	
	Dr D Fraser	
Lay Members	Mr B Nimick	
	Mr D Simpson	
Ex-officio:	Dr S Mitchell	Civil Aviation Authority
	Ms J Chandaman	Medical Licensing Policy, DVLA
	Dr B Wiles	Senior Medical Adviser, DVLA
	Dr A Kumar	Panel Secretary/Medical Adviser, DVLA
	Mr Jones	

1. Apologies for absence

Professor M Cowie, Dr A Kelion and Mr M Gannon.

2. Chairman's remarks

The Chairman welcomed the Panel members and the guest speaker.

3. Minutes of meeting of 18 April 2013

The minutes of the meeting of 18 April 2013 were agreed upon and accepted as accurate.

4. Matters arising

4ii Aortic stenosis: Group 2 licence standards

It was agreed in the April 2013 Panel meeting that individuals with asymptomatic severe aortic stenosis would need to meet the exercise tolerance test requirements before a Group 2 licence can be issued. Individuals who were unable to undertake an exercise tolerance test due to any reason, would not be issued or renewed a Group 2 licence.

The Medical Adviser Group at the DVLA were seeking Panel advice on whether these individuals who were unable to undertake exercise tolerance testing due to mobility issues, should be offered an alternative cardiac functional test just as individuals in the coronary artery disease group are offered alternative cardiac functional tests.

This issue was discussed at length. Panel agreed that if these individuals with severe aortic stenosis are unable to undertake an exercise tolerance test, a Group 2 licence will have to be revoked/refused as currently there is no alternative way to assess their cardiac function other than the exercise test.

Discussion points:

Severe aortic stenosis has a bad prognosis and it is likely that in individuals with poor mobility, symptoms of aortic stenosis are masked/under reported due to the sedentary lifestyle. It is very important to assess cardiac function in these individuals. There was a suggestion that there should be separate guidelines for severe aortic stenosis and the guidance could be worded as "*individuals with severe aortic stenosis should not be driving Group 2 vehicles unless they can meet the exercise tolerance test requirements*". However, this would not take into account the symptom profile of the individual and as currently all symptomatic aortic stenosis individuals are debarred from driving Group 2 vehicles, there is no need for them to meet the exercise test requirements. Hence, it was agreed to leave the wording as recently amended in the 'At a glance Guide to the current Medical Standards of Fitness to Drive'.

The issue of left ventricular function in severe aortic stenosis was also discussed. As per the current clinical guidelines for the management of asymptomatic severe aortic stenosis, if the left ventricular function is depressed (less than 50%) they are considered to be at high risk for an event and referred for surgery. A scenario was discussed – an individual with severe aortic stenosis, asymptomatic, manages 9 minutes of an exercise tolerance test and the left ventricular function is 40% or more but less than 50%, he/she would meet the Group 2 criteria and would be issued with a Group 2 licence even though they have severe aortic stenosis and depressed left ventricular function (less than 50%). The consensus was that if an individual can complete 9 minutes of the Bruce protocol exercise tolerance test without symptoms and without ECG changes, they do demonstrate acceptable cardiac function for a Group 2 licence entitlement. It was also pointed out that this would not be a very common occurrence.

5. Minutes of the Chairmen's meeting of 20 June 2013

The Chairman briefed the Panel on the main issues from the minutes of this meeting.

i. Mr Bryan Jones (Business Support, DVLA) gave an update on the Managed Medical Services. Panel were made aware that there is an increasing volume of work in the Drivers' Medical Group, delay in getting medical information/test results leading to huge backlogs in the workload. The aim of the Managed Medical Services is to deliver a better service to DVLA. The contract for the Managed Medical Services will be awarded to the bidder successful in the tender process and this supplier/company will be responsible mainly for the administrative aspects of the referral process for medical investigations/appointments. Panel were re-assured that the medical aspects of the referral process, that is, referral letters, criteria and licence standard setting would still lie in the domain of the Drivers' Medical Group. There will not be any change in the structure of the DVLA Medical Adviser Group and the Secretary of State's Honorary Medical Advisory Panels as a result of the Managed Medical Services.

Mr Jones did advise the Panel that currently the Managed Medical Services process is on hold/delayed due to the evolving changes in the strategic direction of the DVLA Management Group.

The Chairman queried whether the single supplier (under the Managed Medical Services) would be managing referral for cardiac functional tests (ETT, stress echocardiogram or MPS etc) and this was confirmed to be the case. Panel were re-assured that there is a provision in the contract for the supplier to adapt their process to any changes in standards/criteria following Panel meetings and advice.

ii. **Research**: The Panel Chairman mentioned that in the past it has been difficult for the Cardiovascular Panel to get their research proposals accepted by the Department for Transport Research Group as randomised control trials would not meet DfT research criteria. The Chairman suggested 'multiple medical conditions in relation to driving' as one of the research projects, however, he was advised by the DVLA that data availability would be a limitation.

Mr Jones mentioned that there is ongoing consultation with the Neurology Panel to analyse approximately 4,500 police notifications to look at multiple medical conditions, the data could also be extracted from the CDT (Carbohydrate Deficient Transferrin) pilot studies. Once the above process is finalised this could be shared with the other panels.

6. Panel attendance

The Chairman acknowledged that the Cardiovascular Panel is usually well attended. He mentioned that although he appreciates it is becoming increasingly difficult for clinicians to attend to non clinical duties, it is important to attend the Panel meetings regularly in order to keep the continuity of the discussion items on the agenda. If a

member finds it repeatedly difficult to attend the Panel meetings, they must make the Panel aware of this so that solutions could be looked for.

7. Coronary CT angiography: Group 2 licence standards

It was agreed at previous Panel meetings (September 2012, April 2013) that in individuals with no known coronary artery disease (acute coronary event/angioplasty/coronary artery bypass graft), if CT angiography shows no stenosis more than 50%, a Group 2 licence could be issued without the need for functional testing. This matter was further discussed in great detail to reach a consensus regarding the duration of a Group 2 licence in these individuals and the need for a cardiac functional test as a follow-up on renewal if needed.

Conclusion:

Panel agreed that if the diagnosis of chest pain under investigation is uncertain/unknown/atypical chest pain and CT angiography shows less than 50% stenosis, then a Group 2 licence could be issued without further functional assessment and no further follow-up needed unless any new information is received. However, if there is known coronary artery disease (history of acute coronary syndromes/angioplasty/CABG) and/or a clinical diagnosis of angina has been made, cardiac functional assessment would be needed for Group 2 licensing purposes even though CT coronary angiography may show less than 50% stenosis in coronary arteries.

Discussion point:

There was agreement that individuals with CT coronary angiography showing less than 50% stenosis in coronary arteries are in a low risk group for a sudden cardiac event (based on previous discussions and literature evidence), however, if these individuals do have coronary artery disease evident on the CT angiography, they do need to be followed-up as coronary artery disease is a progressive condition, and

there is a lack of follow-up data regarding the warranty period of CT angiography in this group of individuals. Furthermore, it was pointed out that the data used in the study for CT angiography showing less than 50% stenosis was mainly from individuals with atypical angina/uncertain diagnosis. Hence the advice that individuals with less than 50% coronary artery stenosis on CTA should have no further cardiac functional assessment should be reserved for this group of individuals who do not have a clear/confirmed diagnosis of angina. It was mentioned that it was quite possible to have non obstructive coronary artery disease but a positive functional test due to myocardial ischaemia which is what DVLA is trying to exclude before issuing a Group 2 licence. Panel maintained that a satisfactory 9-minute exercise tolerance test is a good prognostic indicator for coronary artery disease. It was also pointed out that there is a significant difference between the demography of the LGV and PCV (e.g. coach) driver which needs to be borne in mind when setting standards for the follow-up of individuals with coronary artery disease.

The Civil Aviation Authority approach on CT angiography findings is that if there is any finding other than minor coronary artery disease, the individuals are referred for exercise tolerance testing and followed-up with ETT on each renewal. This is based on the rationale that coronary artery disease is a progressive disease.

8. Cardiac MRI: Presentation by Dr Mark Westwood, Consultant Cardiologist, London Chest Hospital

Panel thanked Dr Westwood for a very comprehensive presentation and overview on the role of cardiac MRI in the current clinical practice.

Conclusion:

Currently DVLA does not need to routinely commission cardiac MRI as a test for measuring left ventricular function or assessing reversible ischaemia as exercise tolerance testing, stress echocardiogram/myocardial perfusion scan is in place for the above indication for Group 2 licensing purposes. However, if a cardiac MRI has

been performed already in the clinical practice and a specialist report is made available to DVLA, then DVLA would consider this report and if needed refer to an expert for an opinion.

The measurement of left ventricular ejection fraction at a value of 40% or more as measured by a cardiac MRI would be acceptable for Group 2 licensing purposes. For the purpose of reversible ischaemia, standards similar to the stress echocardiogram would be acceptable for a stress cardiac MRI.

Main relevant points from Dr Westwood's presentation:

Currently Germany and the UK are 2 of the biggest users of cardiac MRI (CMR) per Capita. The National Audit in 2011 showed that 60 centres in the UK are currently performing cardiac MRI with a 10-15% per annum growth at most centres and this is a sustained growth. The main indications for cardiac MRI in clinical practice:

i. Ventricular function (left ventricle and right ventricle) – accepted Gold standard method;

ii. Assessment of myocardial infarction (timing of the myocardial infarction, area involved, micro-vascular obstruction) – by Gadolinium enhancement;

iii. Ischaemia assessment: stress perfusion studies (Adenosine mostly used in clinical practice);

iv. Cardiomyopathies;

v. Congenital heart disease.

The biggest study in this area is the Euro CMR Registry.

Coronary artery disease and abnormal CMR (function and perfusion) has an event

rate of approximately 2.7% per year and a normal CMR (function and perfusion) has an event rate of 1% per year. If there is an abnormal CMR with respect to delayed Gadolinium enhancement, there is no prognostic data in quantative values at present.

Ventricular function (LV and RV): It is difficult to compare the numerical values of ejection fraction as measured by CMR with those obtained by other modalities, that is, no conversion formula available due to lack of geometric assumption. The method to obtain the left ventricular ejection fraction in CMR is completely different to that of a MUGA scan or a stress echocardiogram. The normal range of LVEF as measured by CMR is 55-56%. The reference range for normal values may be slightly different at different centres due to the differences in measurement techniques (cavity vs/ cavity + papillary muscle function). As inter-centre variability is well known, if there is conflicting evidence regarding the CMR LVEF values, a Panel referral would be needed in such cases.

Perfusion image: Stress perfusion studies usually done with Adenosine to look for a perfusion/filling defect in the poorly perfused segments following IV contrast injection. Beta blocker is usually not stopped in a routine clinical practice.

The absolute quantification of ischaemic segments is extremely difficult with CMR as it is a comparative study, for example, to compare normal tissue with infarcted or ischaemic tissue. Quantification of ischaemic segments is done in terms of mild, moderate and severe ischaemia. It was pointed out that the sensitivity and the negative predictive value of CMR is much better than the SPECT studies.

The data to predict mortality related to an acceptable cut-off value of LVEF as measured by CMR is similar to those of other modalities, hence a 40% LVEF as measured by CMR would be acceptable for Group 2 licensing purposes. It is not very common in clinical practice at present to request a CMR when conflicting values of LVEF is obtained by different methods, CMR is used more commonly in the ICD implantation decision-making process.

9. Surgery for valvular heart disease: Group 1 and Group 2 licence standards

There was a brief presentation by Mr Goodwin to highlight the main issues with valvular heart surgery in relation to fitness to drive. Based on the presentation and figures discussed, Panel agreed that the standards for Group 1 and Group 2 licence for valvular heart surgery should be similar to those of coronary artery bypass graft except that for a Group 2 licence, if there is isolated valvular heart disease there will not be a need to repeat an exercise tolerance test every 3 years. A satisfactory post-operative echocardiogram and a D4 renewal medical examination when appropriate would be sufficient. The 'At a glance Guide to the current Medical Standards of Fitness to Drive' would need to be amended to reflect these standards.

Important Relevant points:

Approximately 10,000 heart valve operations per year are performed in the UK (excluding TAVI). This has gone up by 50% in the last 10 years and the numbers are rising slowly. At present, TAVI (transcatheter aortic valve implantation) is generally indicated in elderly patients with co-morbidities, this might well be extended to younger age groups in future. Germany followed by the UK is doing most the TAVI procedures, and in Germany most of the aortic stenosis surgery is done by TAVI.

The main issues for safety to drive are as follows:

i. Physical recovery from the surgery - a conventional sternotomy takes about 3 months to heal completely, whereas minimally invasive approaches to valve surgery (eg. a mini sternotomy) may have a quicker recovery period. However, as there is no hardcore evidence to support this and to keep the guidelines simple and consistent, a 3-month period off driving following valvular heart surgery would seem reasonable for Group 2 licence purposes.

Other relevant issues to driving in relation to heart valve surgery are:

Resolution of symptoms (tiredness, angina), post operative risk of death, stroke and arrhythmia. The risk of death post operatively (up to the first 30 days post operative) depending upon the operation performed – around 1.5% for straightforward Aortic valve replacement (AVR) or mitral valve repair (MVR) rising to 7.6% for an MVR + CABG (UK 2011 figures). Most of this occurs in hospital. For AVR +CABG, especially around 30-35% can occur in the first month post discharge – giving a sudden rate of 0.5-1% for AVR + CABG. The risk factors for this appear to be pre operative severity of left ventricular hypertrophy and post operative evidence of bundle branch block. Stroke occurs in around 1-2% post operatively and is usually within the early days whilst still in hospital. Arrhythmias are very common in the post operative period occurring in about 25-40% of patients. Most commonly this is atrial fibrillation within the first 10 days post operatively and usually requires drug therapy. Failure to resolve is usually treated with anticoagulation and cardioversion. In most cases it resolves by the 4th to 6th week post operatively. The other major complication is complete heart block post operatively in around 3-4% of patients and requires pacemaker insertion. In some cases visual symptoms and cognitive problems have also been reported in the first 2-3 weeks following coronary artery bypass graft or valvular surgery, however, most of these are resolved by 6 weeks.

Keeping in view all the above figures, Panel agreed that it would be reasonable to have a minimum 4 weeks off driving post valvular surgery, for Group 1 licensing and 3 months off driving post surgery for Group 2 licence purposes. A satisfactory post operative echo would be reasonable upon first notification however, it would not be essential to repeat this on renewal unless there are reasons of concern. A satisfactory medical follow-up would be sufficient on a Group 2 licence renewal (a D4 medical examination).

Panel agreed to review the need for separate guidelines for TAVI and minimally invasive surgery if in future there is further evidence to support this.

10. Progress of the European Union Cardiology Working Group

(Annex III EC Directive)

Dr Kumar gave an update regarding the progress of the European Union Cardiology Working Group to the Panel.

The Working Group were given a deadline at a short notice by the Driving Licence Committee for the submission of their recommendation text for the legal purpose in July 2013.

The advice from the Driving Licence Committee was to have the text in a very simplified/concise form for the legal purpose and to include all the detailed text in the actual Working Group report. The text for the legal purpose has been prepared by the Working Group and the detailed report is going to be finalised by the end of September 2013.

The Chairman of the Working Group has advised that there are still some disagreements within the group on specific items. Whilst these would need to be agreed upon before the final report is ready, he appreciates that some issues may remain unresolved and in these cases the majority opinion will be taken into consideration.

The legal text may need to be amended accordingly if needed, before the final presentation to the Commission in December 2013.

The Chairman also suggested that it would be helpful to have a specific 'expert opinion' on the unclear topics, for example, by the Chairman of the Writing Committee of the corresponding guidelines.

11. Case for discussion

Two cases were discussed (non compaction cardiomyopathy and ventricular tachycardia) and advice was given by Panel in both cases.

12. Any other business

i. Fractional flow reserve (for Group 2 licence purpose): Panel members agreed that the acceptable value for allowing a Group 2 licence should be changed from 0.75 to 0.8 to reflect the currently acceptable prognostic values in clinical practice.

ii. Marfan's syndrome. Dr Freeman pointed out that the standard as in the 'At a glance Guide to the current Medical Standards of Fitness to Drive' should include 'other Inherited Aortopathies' under the same heading as Marfan's syndrome. At a Glance would be amended to reflect the above.

13. Date of next meeting

The proposed date for the Spring meeting is 6 March 2014, however, it could be changed to 20 March 2014 depending upon the availability of some Panel members.

DR A KUMAR MBBS MRCGP
Panel Secretary

27 September 2013